



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,550	10/26/2001	Eldon H. Nyhart JR.	41594-200407	3390
23643	7590	11/03/2006	EXAMINER	
BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,550

Applicant(s)

NYHART, ELDON H.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-65 and 104-140 is/are pending in the application.
- 4a) Of the above claim(s) 107-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-65 and 104-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 08/24/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08/24/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. The signed duplicate IDS filed 08/24/06 has been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 57-59,62,64,105-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman et al. (US 6,086,582).

Altman et al. disclose a method of providing a compound to a system comprising a catheter having a drug which is releasably captured in the matrix, a source of electrical energy 1052 which is activated to release the drug from the matrix 1060, a controller which senses electrical activity of the heart and responds by injecting delivery of the drug or goes into monitoring mode depending on the sensed electrical activity. See column 14, lines 7-47 and col.14, line 66 to col. 15, lines 47. With respect to

Application/Control Number: 10/045,550
Art Unit: 3763

claims 64, Altman et al. disclose the releasing of the drug depends on the sensed electrical activity and as such, it is considered to releasing predetermine amounts of compounds at variable intervals. See column 16, lines 2-8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,086,582) in view of Chupakhin et al. (US 6,028,068).

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. However, Altman et al. does not disclose the therapeutic agent is anesthetic and the system to be the neurological system. Chupakhin et al. teach 6H-1,3,4-thiadiazin-2-amines drugs used in medicine acting as anesthetics, cardiovascular and hypometabolic agents. Specifically, Chupakhin et al. teach that anesthetic agents act as respiratory and cardiovascular depressants. Further, agents have been identified as having anesthetic and cardiovascular property, which are used in brain and myocardial infarction. Anesthetics are a drug class which is well known for acting on the

neurological system. It would have been obvious to one of ordinary skill in the anesthesia art to substitute the cardiovascular drug of Altman et al. with the 6H-1,3,4-thiadiazin-2-amines which could treat the patient in a life-threatening situation with the properties of the being an anesthetic and cardiovascular agent which act on the circulatory and neurological system.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,086,582) in view of Donatsch et al. (US 4,789,673).

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. However, Altman et al. is silent to a neurotransmitter as an agent in the neurological system of the biological unit. Donatsch et al. teach serotonin M receptor antagonists for the treatment of pain, migraine, vascular and treatment of heart circulation disorders. Serotonin receptors are located in the nervous system of the GI track, the heart, the bladder and the adrenal glands. It would have been obvious to one of ordinary skill in the medical art to substitute the cardiovascular drug of Altman et al. with another cardiovascular drug such as the Serotonin M receptor antagonist of Donatsch et al. in order to treat heart circulation disorders.

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,086,582).

Altman et al. disclose the invention as substantially claimed. See above. However, Altman et al. is silent to the control signal having a frequency content of less than about 1 Hz. It would have been obvious to one of ordinary skill in the art at the

Art Unit: 3763

time the invention was made to modify the frequency to about 1 HZ since it lacks criticality and this parameter is deemed matters of choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Claims 65 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,086,582) in view of Ellinwood, Jr. (US 4,146,029).

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. Altman et al. teach a controller for releasing an amount of drug at variable intervals. However, Altman et al. is silent to releasing variable amounts of the compound at predetermined intervals or releasing variable amounts of the drug at variable intervals. Ellinwood, Jr. teaches a programmable controller for a medication system. See figures 1-11. Ellinwood, Jr. teaches 1/sensing, timed evaluation, with decision control, 2/periodic sensing and screening control, 3/periodic sensing, data evaluation with dosage control, 4/periodic sensing, data evaluation and alternate dosage selection, and 5/sensing, controlled same dosage with different amounts for different conditions. See column 3, lines 9-46, and column 4, lines 39-42. Ellinwood, Jr. further discloses that a large number of variables can be programmed to match both the immediate and changing conditions of a wide range of patient needs. Thus, it would have been obvious to modify the predetermined amount of the drug and/or the interval

Art Unit: 3763

time of Altman et al. with variable amounts of drug and/or variable interval times as taught by Ellinwood, Jr. in order to provide a more effective treatment method for the varying need of the patient condition.

Response to Arguments

Applicant's arguments filed 08/24/06 have been fully considered but they are not persuasive. Applicant's argument that Altman et al. is silent or does not teach the limitation of "preparing a control signal using fractal mathematics" is not convincing. The Examiner is taking the position that the control signal is prepared by using fractal mathematics. It is being considered that the computer/controller is inherently producing fractal mathematics since fractals are generated by an iterative process - doing the same thing again and again. The computer/controller has this factor built in. Fractals also have the property that when you magnify them they still look much the same. The device of Altman produces the same control signal to release the compound. Further, if fractal mathematics is considered to be calculations based on fractions, any integer is considered to be a fraction or could be represented as a fraction.

Conclusion

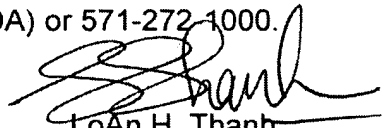
Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT